

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/004580

International filing date (day/month/year)
29.10.2004

Priority date (day/month/year)
30.10.2003

International Patent Classification (IPC) or both national classification and IPC
A23L1/015, A61K35/78, A23C9/00

Applicant
LODERS CROKLAAN BV

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/004580

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 21 in respect of industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 21 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/004580

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-25
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-25
Industrial applicability (IA)	Yes: Claims	1-20,22-25
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 21 of the present application relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to industrial applicability of the said subject-matter of this claim.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 For the assessment of the subject-matter of present claim 21 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States (see also Item III of the present written opinion). The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable claims directed to a method of medical treatment.
- 2 Reference is made to the following documents:
 - D1: US-A-5 607 971 (AL-MAHMOUD MOHSEN ET AL) 4 March 1997 (1997-03-04)
 - D2: US-A-5 466 453 (UCHIDA YUKIO ET AL) 14 November 1995 (1995-11-14)
 - D3: US-A-5 690 984 (LIM JUNG GEUN) 25 November 1997 (1997-11-25)
 - D4: US-B1-6 329 000 (JI LING) 11 December 2001 (2001-12-11)
 - D5: DATABASE FSTA [Online] INTERNATIONAL FOOD INFORMATION SERVICE (IFIS), FRANKFURT/MAIN, DE; 2000, EUN-JU KIM ET AL: "Bread properties utilizing extracts of pine needle according to preparation method." XP002272259 Database accession no. 2000-00-m0004
 - D6: DATABASE FSTA [Online] INTERNATIONAL FOOD INFORMATION SERVICE (IFIS), FRANKFURT/MAIN, DE; 1999, YOUNG-AE OH ET AL: "Effect of addition of water extract of pine needle on tissue of kimchi." XP002272260 Database accession no. 1999-00-j0385
 - D7: WO 02/101025 A (KWON JAY YUNE ;KOREA BIOTECH CORP (KR);

VLADIMIR BAKHAREV A (RU)) 19 December 2002 (2002-12-19)

Novelty

- 3 The subject matter presently claimed is considered to be novel (Art.33(2) PCT). None of the products of the prior art discloses a pine needle extract comprising less than 0.01% isocupressic acid. Reference is made to p.16 and Table 1 of the present application wherein the content of isocupressic acid has been established for several extracts of the prior art (D1 and D4) and for aqueous pine needle extracts with or without ion exchange and carbon black treatment. Similarly, the use of such extracts or methods applying said extracts as well a process for its production is considered to be novel.

Inventive step

- 4 The subject-matter presently claimed is considered not to fulfil the requirements of Art.33(3) PCT.
- 4.1 D1-D7 (for relevant passages please see ISR) disclose independently of each other the use of pine needle extracts for at least one the following purposes:
- reducing blood pressure,
 - preparing healthy food products (such as ice cream),
 - preparing healthy fermented dairy food products
 - preventing hypertension or at least having health indications
 - improving the taste and texture of various food compositions.
- Said documents, however, fail to disclose less than 0.01% of isocupressic acid in spite of the fact that the extracts do contain (implicitly or explicitly) at least one organic acids such as for instance shikimic or quinic acid.
- 4.2 The problem to be solved is to provide alternative healthy food compositions, dairy products and beverages and methods / uses therefore.
- 4.3 Starting from each one of the documents of the prior art, no surprising effect can be seen in the solution proposed by the present application, i.e. using pine needle extracts with low isocupressic acid contents. This is in particular valid as far as the technical effect concerns textural or sensoric properties of the products.
- 4.4 Also the assertion on p.2, last paragraph of the application as internationally filed, that it was not known that low isocupressic acid pine needle extracts are therapeutically effective cannot be followed. On the contrary, D4 shows that pine needle extracts with particularly low amounts of isocupressic acid are effective against hypertension, diabetes, high blood viscosity, hyperlipidaemia to name a few. From D4 the one skilled in the art can only derive the teaching that low

amounts of isocupressic acid do not influence therapeutic properties of pine needle extracts.

Re Item VIII

Certain observations on the international application

- 1 The following clarity deficiency are noted (Art.6 PCT)
 - 1.1 Although claims 11, 19, 21 and 23 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness.
 - 1.2 The subject-matter of present claims 3 and 4 is unclear as it is not readily clear to the one skilled in the art what falls within and what is without the ambit of the claim.
 - 1.3 The subject-matter of present claim 16 is formulated as a result to be achieved.